ALBEMARLE® CORPORATION

451 Florida Street
Baton Rouge, Louisiana 70801-1765

Telephone: 225-388-8011
Facsimile: 225-388-7686

Health and Environment Department
Toxicology and Regulatory Affairs
Facsimile: 225-388-7046

December 3, 2002

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Fax: 301-827-6870

Re: Albemarle Letter Dated October 24, 2002

This is a request to amend the subject letter (copy attached) to change the docket reference number from 77N-0094 to 77N-094i. Please kindly make the appropriate docket file transfer.

If you have any questions, please call me at 225-388-7650.

Sincerley,

Louise L Wen

77N-094I EXT 2

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October 24, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket 77N-0094:
Request for an Extension of the Comment Period to the Proposed Amendment of the Tentative Final Monograph for Internal Analgesic, Anti-pyretic and Anti-rheumatic Drug Products for Over-The-Counter Human Use

Dear Sir/Madam:

Albemarle Corporation, a major domestic producer of Ibuprofen active pharmaceutical ingredients, hereby requests the Food and Drug Administration (FDA) for a 90-day extension to the comment period for the proposed amendment of the Tentative Final Monograph (TFM) to include ibuprofen 200 mg tablets for Over-the-Counter (OTC) human use. The proposed rule was published in the Federal Register on August 21, 2002 with a comment period due to close on November 19, 2002.

It recently came to our attention that some foreign ibuprofen tablets may contain toxic metals such as lead and chromium. This information led us to analyze readily available bulk ibuprofen from western producers including samples produced by Albemarle Corporation. We found no lead or chromium at the limits of detection by ICP analysis in the tested western produced bulk ibuprofen. However, preliminary analytical data of some ibuprofen tablets obtained off shore have shown levels of lead and chromium that would be a toxicity concern to the consumer. In an effort to confirm our findings, we are in the process of obtaining additional ibuprofen tablets from different countries in both Europe and Asia. Therefore, Albemarle will need additional time to obtain the samples and conduct analytical tests to confirm the levels of lead and chromium in ibuprofen tablets.

Great efforts have been made by both FDA and EPA to reduce lead exposures during the past two decades. Lead is no longer allowed in gasoline, house paints, and food/beverage cans. In addition, FDA has set and tightened regulatory limits on the amount of lead that may be leached from ceramic ware in an attempt to lower lead exposure. Since ibuprofen is frequently taken to relieve chronic pain and in many instances for extended period, the presence of lead in ibuprofen tablets is an important factor in the FDA assessment of safety. We believe the FDA would be interested in this new information. As such, results of our analysis will be made available to the Agency upon completion.

It could be reasonably assumed that once the TFM is finalized and the OTC ibuprofen is no longer subject to ANDA approvals by the FDA, these lead/chromium containing foreign produced ibuprofen tablets will be readily available in the U.S. market in light of the public's interest to reduce total drug costs including those sold over-the-counter. The potential of incremental lead/chromium intake from these imported ibuprofen tablets by adults who are on daily regimen to relieve chronic pain may pose a safety concern not previously addressed.

Albemarle Corporation appreciates the opportunity to comment on the proposed rule. We look forward to providing the FDA with our findings of lead and chromium levels in the ibuprofen tablets. In the meantime, we believe our preliminary finding is of significant importance such that a 90-day extension be granted to allow Albemarle to confirm the results before submitting our comments to the TFM amendment.

If you have any questions, please feel free to contact me at 225-388-7650.

Sincerely,
Albemarle Corporation

Louise L. Wen, Ph.D.
Manager, Regulatory Affairs

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